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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/553,993	GUNDERSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *3/03* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 2 December 2002, 14 March 2003 and 27 June 2003. Claims 1-14 are canceled. Claims 15-29 are pending.

All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 26 July 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection necessitated by amendment are discussed.

Claims 15-29 are under prosecution.

Claim Objections

2. Claims 15-21 and 24 are objected to because of the following informalities:

Claims 15-21 are each objected to for being dependent on Canceled Claim14. For purposes of examination, the claims are interpreted as being dependent on Claim 29.

Claims 17 and 24 are each objected to for the repeated phrase "wherein said".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-28 are indefinite in Claim 22, step a) for the recitation "the first primer" because the recitation lacks proper antecedent basis in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 29, 15-17, 19-20, 22-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macevicz (U.S. Patent No. 6,280,935, filed 4 June 1998) in view of Ullman et al (U.S. Patent No. 5,185,243, issued 9 February 1993).

Regarding Claim 29, Macevicz teaches a method of detecting a target nucleic acid sequence, said method comprising: hybridizing a first primer portion comprising an adapter sequence (ligation probe) to a target sequence; hybridizing a second primer to a second portion of said target sequence; ligating said first and second primer to form a modified primer; contacting said modified primer with an array comprising: a substrate with a surface comprising discrete sites and a population of microspheres comprising a first nucleic acid capture probe that hybridizes to said adapter sequence wherein said microspheres are distributed on said surface and detecting the presence of said target sequence (Column 34, lines 11-38). Macevicz does not teach that the first and second portions of the target sequences are non adjacent and extending either the first or second primer toward the other.

However, Ullman et al teach a similar method comprising: hybridizing a first primer portion to a target sequence; hybridizing a second primer to a second portion of said target sequence wherein the first and second target regions are not adjacent; extending one of the primer toward the other and ligating said first and second primer to form a modified primer and capturing the modified primer (Column 4, line 45-Column 6, line 5; and Column 9, line 59-Column 10, line 18) wherein the extension of non-adjacent primers eliminates the need to identify the diagnostic sequence thereby facilitating diagnostic detection and increasing the specificity and sensitivity of diagnostic detection (Column 4, lines 3-12).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the primers of Macevicz by designing primers that hybridize to non-adjacent target positions as taught by Ullman et al for the expected benefit of eliminating the need to identify the diagnostic sequence thereby facilitating diagnostic detection and further increasing the specificity and sensitivity of diagnostic detection as taught by Ullman et al (Column 4, lines 3-12).

Regarding Claim 15, Macevicz teaches the method further comprising detecting a second target sequence (i.e. population of library members) thereby comprising hybridizing

third and forth primers to first and second portions of the second target; contacting with said array and detecting the presence of said second target (Column 16, lines 12-67).

Regarding Claim 16, Macevicz teaches the method wherein the modified primer is amplified (Column 16, line10-Column 19, line 49).

Regarding Claim 17, Macevicz discloses the method wherein the detecting is done by hybridizing a labeled probe (Column 24, lines 63-67). And Ullman et al teach their similar method wherein the detecting is done by hybridizing a labeled probe (Column 22, lines 9-42).

Regarding Claim 19, Macevicz discloses the method wherein said discrete sites comprise wells (Column 32, lines 5-10).

Regarding Claim 20, Macevicz discloses the method wherein the detecting is done by hybridizing a labeled probe (Column 24, lines 63-67). And Ullman et al teach their similar method wherein the detecting is done by hybridizing a labeled probe (Column 22, lines 9-42).

Regarding Claim 22, Macevicz teaches a method of detecting a plurality of target nucleic acid sequences, (i.e. population of library members, Column 16, lines 12-67) said method comprising: hybridizing a first primer portion comprising an adapter sequence (ligation probe) to a target sequence; hybridizing a second primer to a second portion of said target sequence; ligating said first and second primer to form a modified primer; contacting said modified primer with an array comprising: a substrate with a surface comprising discrete sites and a population of microspheres comprising a first nucleic acid capture probe that hybridizes to said adapter sequence wherein said microspheres are distributed on said surface and detecting the presence of said target sequence (Column 34, lines 11-38). Macevicz does not teach that the first and second portions of the target sequences are non adjacent and extending either the first or second primer toward the other.

However, Ullman et al teach a similar method comprising: hybridizing a first primer portion to a target sequence; hybridizing a second primer to a second portion of said target sequence wherein the first and second target regions are not adjacent; extending one of the

primer toward the other and ligating said first and second primer to form a modified primer and capturing the modified primer (Column 4, line 45-Column 6, line 5; and Column 9, line 59-Column 10, line 18) wherein the extension of non-adjacent primers eliminates the need to identify the diagnostic sequence thereby facilitating diagnostic detection and increasing the specificity and sensitivity of diagnostic detection (Column 4, lines 3-12).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the primers of Macevicz by designing primers that hybridize to non-adjacent target positions as taught by Ullman et al for the expected benefit of eliminating the need to identify the diagnostic sequence thereby facilitating diagnostic detection and further increasing the specificity and sensitivity of diagnostic detection as taught by Ullman et al (Column 4, lines 3-12).

Regarding Claim 23, Macevicz teaches the method wherein the modified primer is amplified (Column 16, line10-Column 19, line 49).

Regarding Claim 24, Macevicz discloses the method wherein the detecting is done by hybridizing a labeled probe (Column 24, lines 63-67). And Ullman et al teach their similar method wherein the detecting is done by hybridizing a labeled probe (Column 22, lines 9-42).

Regarding Claim 26, Macevicz discloses the method wherein said discrete sites comprise wells (Column 32, lines 5-10).

Regarding Claim 27, Macevicz discloses the method wherein the detecting is done by hybridizing a labeled probe (Column 24, lines 63-67). And Ullman et al teach their similar method wherein the detecting is done by hybridizing a labeled probe (Column 22, lines 9-42).

7. Claims 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macevicz (U.S. Patent No. 6,280,935, filed 4 June 1998) in view of Ullman et al (U.S. Patent No. 5,185,243, issued 9 February 1993) as applied to Claims 29 and 22 above and further in view of Walt et al (U.S. Patent No. 6327,410, filed 11 September 1998).

Regarding Claims 18 and 25, Macevicz teaches a method of detecting a target nucleic acid sequence and a library of targets, said method comprising: hybridizing a first primer portion comprising an adapter sequence (ligation probe) to a target sequence; hybridizing a second primer to a second portion of said target sequence; ligating said first and second primer to form a modified primer; contacting said modified primer with an array comprising: a substrate with a surface comprising discrete sites and a population of microspheres comprising a first nucleic acid capture probe that hybridizes to said adapter sequence wherein said microspheres are distributed on said surface and detecting the presence of said target sequence (Column 34, lines 11-38). And Ullman et al teach a similar method comprising: wherein the first and second target regions are not adjacent; extending one of the primer toward the other and ligating said first and second primer to form a modified primer and capturing the modified primer (Column 4, line 45-Column 6, line 5; and Column 9, line 59-Column 10, line 18) wherein the extension of non-adjacent primers eliminates the need to identify the diagnostic sequence thereby facilitating diagnostic detection and increasing the specificity and sensitivity of diagnostic detection (Column 4, lines 3-12).

Macevicz further teaches the substrate is selected from one of many known in the art and is selected based on efficiency and optical properties (Column 14, line 61-Column 15, line 23, especially lines 17-21) but they do not specifically teach the support is a fiber optic bundle. However, Walt et al teach a similar method of target detection comprising contacting a modified target sequence with an array comprising a substrate with a patterned surface comprising discrete sites and a population of microspheres comprising a first and second subpopulation capture probe wherein the microspheres are distributed on said patterned surface and

detecting the presence of said first modified target sequence wherein said target is labeled prior to contacting (Column 21, lines 17-25) wherein they specifically teach that their fiber optic bundle support, in addition to providing optical properties which permit optical resolution of tens of thousands of target sequences, is efficient and inexpensive (Column 4, lines 35-58 and Column 5, lines 24-30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the fiber optic support of Walt et al to the support of Macevicz based on the suggestion of Macevicz to apply known supports based on efficiency and optical properties (Column 14, line 61-Column 15, line 23, especially lines 17-21) and for the expected benefits of exceptional efficiency and optical properties as taught by Walt et al (Column 4, lines 35-58 and Column 5, lines 24-30).

8. Claims 15-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany et al. (U.S. Patent No. 6,027,889, filed 28 May 1997) in view of Ullman et al (U.S. Patent No. 5,185,243, issued 9 February 1993) and Walt et al. (U.S. Patent No. 6,023,540, filed 14 may 1997).

Regarding Claim 29, Barany et al. teach a method of detecting a target nucleic acid sequence comprising: hybridizing a first primer to a first portion of a target sequence wherein said first primer further comprises an adapter sequence; hybridizing a second primer to a second portion of said target sequence; ligating said first and second primers to form a modified primer; contacting said adapter sequence of said modified primer with an array comprising: a substrate with a surface comprising discrete sites comprising at least a first sub-population comprising a first capture probe, such that said first capture probe and said

modified first target nucleic acid sequence form a hybridization complex; and detecting the presence of said modified first target nucleic acid sequence (Column 26, line 37-Column 27, line 19 and Claim 13). The extra method steps of Barany et al. are encompassed by the open claim language "comprising" of the instant claims.

Barany et al. do not teach the method wherein the primers are not adjacent. However, Ullman et al teach a similar method comprising: wherein the first and second target regions are not adjacent; extending one of the primer toward the other and ligating said first and second primer to form a modified primer and capturing the modified primer (Column 4, line 45-Column 6, line 5; and Column 9, line 59-Column 10, line 18) wherein the extension of non-adjacent primers eliminates the need to identify the diagnostic sequence thereby facilitating diagnostic detection and increasing the specificity and sensitivity of diagnostic detection (Column 4, lines 3-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the primers of Barany et al by designing primers that hybridize to non-adjacent target positions as taught by Ullman et al for the expected benefit of eliminating the need to identify the diagnostic sequence thereby facilitating diagnostic detection and further increasing the specificity and sensitivity of diagnostic detection as taught by Ullman et al (Column 4, lines 3-12).

Barany et al. do not teach the method wherein the array further comprises a population of microspheres comprising the at least first sub-population wherein said microspheres are distributed on said surface. However, Walt et al. teach a similar method for detecting a target nucleic acid sequence comprising: contacting said first target nucleic acid sequence with an array comprising: a substrate with a patterned surface comprising discrete sites; and a population of microspheres comprising at least a first sub-population comprising a first capture probe such that said first capture probe and said first target nucleic acid sequence form a hybridization complex, wherein said microspheres are distributed on said surface (Column 4, lines 4-14); and detecting the presence of said first target nucleic acid sequence

(Column 10, lines 4-41) wherein microspheres comprising different capture probes are mixed but individually detected and identified allowing for individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use (Column 3, lines 17-30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array of Barany et al. to further comprise microspheres wherein the microsphere are distributed on the array at discrete site and wherein the microspheres comprise the capture probes for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 15, Barany et al. teach the method further comprising detecting a second target sequence (i.e. array) thereby comprising hybridizing third and forth primers to first and second portions of the second target; contacting with said array and detecting the presence of said second target (Fig. 9).

Regarding Claim 16, Barany et al. teach the method wherein the modified primer is amplified (Column 27, lines 1-2).

Regarding Claim 17, Barany et al. teach the method wherein said the detecting is done by hybridizing a labeled probe to the ligated primers (Column 33, lines 16-39).

Regarding Claim 18, Barany et al. teach the substrate is an array (Column 27, lines 10-15) but they do not teach the array is a fiber optic bundle. However, Walt et al. teach the similar method wherein the substrate is a fiber optic bundle (Column 4, lines 4-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array of Barany et al. to further comprise microspheres wherein the microsphere are distributed on a fiber optic bindle substrate for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 19, Barany et al. teach said substrate comprises discrete sites (Column 27, lines 10-15) but they do not teach said discrete sites comprise wells. However, Walt et al. teach the similar method wherein said discrete sites comprise wells (Column 4, lines 4-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the discrete sites on the substrate of Barany et al. to provide microspheres distributed on a substrate at the discrete sites and wherein each discrete site comprises a well for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 20, Barany et al teach the method wherein the detecting is done by labeling amplification products (Column 27, liens 2-19).

Regarding Claim 21, Barany et al teach the method wherein one of the primers is allele specific (Column 25, lines 1-25).

Regarding Claim 22, Barany et al. teach a method of detecting at least sixteen target nucleic acids (i.e. an array, Fig. 9) sequence comprising: hybridizing a first primer to a first portion of a target sequence wherein said first primer further comprises an adapter sequence; hybridizing a second primer to a second portion of said target sequence; ligating said first and second primers to form a modified primer; contacting said adapter sequence of said modified primer with an array comprising: a substrate with a surface comprising discrete sites comprising at least a first sub-population comprising a first capture probe, such that said first capture probe and said modified first target nucleic acid sequence form a hybridization complex; and detecting the presence of said modified first target nucleic acid sequence (Column 26, line 37-Column 27, line 19 and Claim 13). The extra method steps of Barany et al. are encompassed by the open claim language "comprising" of the instant claims.

Barany et al. do not teach the method wherein the primers are not adjacent. However, Ullman et al teach a similar method comprising: wherein the first and second target regions are

not adjacent; extending one of the primer toward the other and ligating said first and second primer to form a modified primer and capturing the modified primer (Column 4, line 45-Column 6, line 5; and Column 9, line 59-Column 10, line 18) wherein the extension of non-adjacent primers eliminates the need to identify the diagnostic sequence thereby facilitating diagnostic detection and increasing the specificity and sensitivity of diagnostic detection (Column 4, lines 3-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the primers of Barany et al by designing primers that hybridize to non-adjacent target positions as taught by Ullman et al for the expected benefit of eliminating the need to identify the diagnostic sequence thereby facilitating diagnostic detection and further increasing the specificity and sensitivity of diagnostic detection as taught by Ullman et al (Column 4, lines 3-12).

Barany et al. do not teach the method wherein the array further comprises a population of microspheres comprising the at least first sub-population wherein said microspheres are distributed on said surface. However, Walt et al. teach a similar method for detecting a target nucleic acid sequence comprising: contacting said first target nucleic acid sequence with an array comprising: a substrate with a patterned surface comprising discrete sites; and a population of microspheres comprising at least a first sub-population comprising a first capture probe such that said first capture probe and said first target nucleic acid sequence form a hybridization complex, wherein said microspheres are distributed on said surface (Column 4, lines 4-14); and detecting the presence of said first target nucleic acid sequence (Column 10, lines 4-41) wherein microspheres comprising different capture probes are mixed but individually detected and identified allowing for individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use (Column 3, lines 17-30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array of Barany et al. to further comprise microspheres wherein the microsphere are distributed on the array at discrete site and wherein

the microspheres comprise the capture probes for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 23, Barany et al. teach the method wherein the modified primer is amplified (Column 27, lines 1-2).

Regarding Claim 24, Barany et al. teach the method wherein said the detecting is done by hybridizing a labeled probe to the ligated primers (Column 33, lines 16-39).

Regarding Claim 25, Barany et al. teach the substrate is an array (Column 27, lines 10-15) but they do not teach the array is a fiber optic bundle. However, Walt et al. teach the similar method wherein the substrate is a fiber optic bundle (Column 4, lines 4-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array of Barany et al. to further comprise microspheres wherein the microsphere are distributed on a fiber optic bindle substrate for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 26, Barany et al. teach said substrate comprises discrete sites (Column 27, lines 10-15) but they do not teach said discrete sites comprise wells. However, Walt et al. teach the similar method wherein said discrete sites comprise wells (Column 4, lines 4-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the discrete sites on the substrate of Barany et al. to provide microspheres distributed on a substrate at the discrete sites and wherein each discrete site comprises a well for the expected benefit of individual identification of thousands of captured target sequences using an apparatus which is easy to manufacture and use as taught by Walt et al. (Column 3, lines 17-30).

Regarding Claim 27, Barany et al teach the method wherein the detecting is done by labeling amplification products (Column 27, liens 2-19).

Regarding Claim 28, Barany et al teach the method wherein one of the primers is allele specific (Column 25, lines 1-25).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this

application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 26, 2003